

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: JERUSSI *et al.*

Application No.: To be assigned
(DIV of 10/278,097, filed October 23, 2002)

Group Art Unit: To be assigned

Filed: Herewith

Examiner: To be assigned

For: METHODS OF TREATING OR
PREVENTING RESTLESS LEG
SYNDROME USING SIBUTRAMINE
METABOLITES (As amended)

Attorney Docket No.: 4821-519-999

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to Applicants' duty of disclosure under 37 C.F.R. § 1.56, enclosed is a list of one hundred forty two (142) references for the Examiner's review and consideration. These references are listed on the enclosed Form PTO-1449 entitled "List of References Cited by Applicant." These references (AA-FL) are listed in reverse-chronological or alphabetical order. Copies of these references are not enclosed as the copies were submitted in connection with U.S. Application No. 09/770,663, filed October 23, 2002, which is the parent of this application, and U.S. Application No. 09/770,663, filed January 29, 2001, which is the grandparent of this application. Copies will be provided, however, upon the Examiner's request.

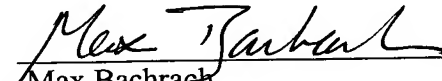
Identification of the foregoing references is not to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application. Consequently, Applicants respectfully decline to use form PTO-1449, since that form identifies all of the references cited therein as "Prior Art." As an alternative, Applicants submit herewith a "revised form PTO 1449" entitled "List of References Cited."

Applicants respectfully request that the Examiner review the references and make them of record by completing and returning the enclosed List of References.

No fee is believed to be due for the submission of this statement since it is being made prior to a first Office Action on the merits in the above case. If any fees are required, however, please charge such fees to Pennie & Edmonds LLP's Deposit Account No. 16-1150.

Respectfully submitted,

Date September 22, 2003


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Enclosure

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

4821-519-999

APPLICATION NO.

To be assigned

APPLICANT

T. Jerussi et al.

FILING DATE

Herewith

GROUP

To be assigned

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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	AB	6,127,363	10/2000	Doherty et al.			
	AC	6,046,242	11/1998	Emmelmann			
	AD	5,795,880	08/1998	Svec et al.			
	AE	5,780,051	07/1998	Eswara et al.			
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							YES	NO
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	BQ	WO 00/56315	09/2000	PCT				
	BR	WO 00/56314	09/2000	PCT				
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	CT	Buckett et al., "BTS 54 524-An Approach to Rapidly Acting Antidepressant," <i>New Concepts in Depression</i> 2 : 167-172 (1988).						
	CU	Bucket et al., "The Pharmacology of Sibutramine Hydrochloride (BTS 54 524), A New Antidepressant which induces Rapid Noradrenergic Down-Regulation", <i>Prog. Neuro-Psychopharmacol. & Biol. Psychiat.</i> 12 : 575-584 (1988).						
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	CW	Butler, D., <i>Facile Cycloalkylation of Arylacetonitriles in Dimethyl Sulfoxide</i> , <i>J. Org. Chem.</i> , 36 :1308-1309 (1971)						
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	CZ	Castello, R.A., et al., <i>Discoloration of Tablets Containing Amines and Lactose</i> , <i>Pharm. Sci.</i> 51(2) :106-108 (1962)						
	DA	Cheetham, S.C., et al., [3 H]Paroxetine Binding in Rat Frontal Cortex Strongly Correlates with [3 H]5-HT Uptake: Effect of Administration of Various Antidepressant Treatments, <i>Neuropharmacology</i> (1993), 32(8) , 737-743						
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	DC	<i>Diagnostic and Statistical Manual of Mental Disorders</i> , Fourth Ed., American Psychiatric Association, (1997).						
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	DO	<i>Introduction to Pharmaceutical Dosage Forms</i> , 4th ed., Lea & Febiger, Philadelphia (1985).						
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	DR	Jeffery et al., <i>Synthesis of Sibutramine, A Novel Cyclobutylalkylamine Useful in the Treatment of Obesity, and its Major Human Metabolites</i> , <i>J. Chem. Soc. Perkin. Trans. 1</i> , 2583-2589 (1996)						

DS	King et al., "Clinical Pharmacology of Sibutramine Hydrochloride (BTS 54524) A New Antidepressant, in Healthy Volunteers," <i>Clinical Pharmacol.</i> 26 : 607-611 (1989).
DT	Kula et al., "Effects of N-Substituted Phenyltetrahydropyridines on Cerebral High-Affinity Synaptosomal Uptake of Dopamine and Other Monoamines in Several Mammalian Species," <i>Life Sciences</i> 34 (26): 2567-2575, (1984).
DU	Luscombe et al., <i>The Contribution of Metabolites to the Rapid and Potent Down-Regulation of Rat Cortical β-Adrenoceptors by the Putative Antidepressant Sibutramine Hydrochloride</i> , Neuropharmacology, Vol. 28, No. 2, (1989) pp 129-134
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DX	Moreau et al., <i>Behavioral Profile of the 5-HT_{1A} Receptor Antagonist (S)-UH-301 in Rodents and Monkeys</i> , Brain Res. Bull., 29 :901-04 (1992)
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FI	Stock, M.J., <i>Sibutramine: A Review of the Pharmacology of a Novel Anti-Obesity Agent</i> , Int'l J. Obesity, 21(Supp. 1):S25-S29 (1997)		
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FK	Wilen et al., <i>Tetrahedron</i> , 2725-36 33(21) (1977).		
FL	Wilen, S.H., <i>Tables of Resolving Agents and Optical Resolutions</i> 268 (E.L. Eliel ed., Univ. of Notre Dame Press, Notre Dame, IN, 1972).		
<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">EXAMINER</td> <td style="width: 50%;">DATE CONSIDERED</td> </tr> </table>		EXAMINER	DATE CONSIDERED
EXAMINER	DATE CONSIDERED		
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>			